JUN - 4 2004

K040654

OPTICAL SENSORS INCORPORATED

Summary of Safety and Effectiveness

Company Name: Optical Sensors Incorporated.
7615 Golden Triangle Drive
Eden Prairie, MN 55344

Contact: Paulita LaPlante, President and CEO
Phone: (952) 947-9545
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Summary Date: March 11, 2004

Trade Name: SensiLase™ PAD 3000 Skin Perfusion Pressure System

Common Name: Blood Flowmeter

Classification Name: 21 CFR 870.2100, Flowmeter, Blood; Class II,
Product Code: DPW; Product Code:

Predicate Device:

510(k) Number: K951486
Manufacture: Vasamedics, LLC
Trade Name: Model PV2000 Vascular Microlaboratory

1.0 Description of Device

The SensiLase™ PAD 3000 (SensiLase™) Skin Perfusion Pressure System provides measurements of Skin Perfusion Pressure (SPP) and Pulse Volume Recording (PVR). Both measurements may be clinically applied to assess perfusion. Both the SPP and PVR measurements are features of the predicate PV2000 device. The same methods are applied for measurement of SPP and PVR as the predicate PV2000.

The SPP measurement is performed by applying a pressure cuff capable of occluding skin blood flow (perfusion). The pressure cuff is inflated until the skin perfusion, as detected by a Laser Sensor Assembly (LSA) underneath the cuff, is determined to be near zero or significantly reduced. The pressure is released until an increase in skin perfusion is determined. The cuff pressure when the skin perfusion increases is the SPP value. SPP is a test used to evaluate peripheral microcirculation.

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The measurement of the pulse volume recording (PVR) waveform is a measure of the pulsatile pressure amplitude resulting from a partially inflated cuff encircling the limb. The PVR is used as a more direct measurement of arterial blockage. The test output is a printout of the waveform, which is interpreted by a vascular specialist.

The clinical application and interpretation of the Perfusion , SPP measurements and interpretation of the PVR Waveform is the same as the predicate PV2000.

2.0 Intended Use

The SensiLase™ PAD 3000 provides a noninvasive measurement of Skin Perfusion Pressure (SPP) and Pulse Volume Recording (PVR) waveforms on extremities of patients.

3.0 Technology

The SensiLase instrument contains a laser diode that is used when performing the skin perfusion pressure measurement. Laser specifications are:

1. Power exiting LSA: 2.3 milliwatts (typical), 3.0 milliwatts maximum.
2. Wavelength: 785 nm
3. Laser Classification per 21CFR1040.10 : Class I
4. Laser Classification per IEC 60825-1: Class 1M

The same technology was applied in the predicate PV2000 device.

4.0 Conclusions

The intended use, technology, features and performance of the SensiLase™ PAD 3000 Skin Perfusion Pressure System are substantially equivalent to the predicate PV2000. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2004

Optical Sensors Incorporated
c/o Mr. Gary Syring
Principal Consultant
Quality & Regulatory, LLC
800 Levanger Lane
Stoughton, WI 53589

Re: K040654
SensiLase™ PAD 3000
Regulation Number: 21 CFR 870.2100
Regulation Name: Flowmeter, Blood, Cardiovascular
Regulatory Class: Class II (two)
Product Code: DPW
Dated: March 11, 2004
Received: March 12, 2004

Dear Mr. Syring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040654

Device Name: SensiLase™ PAD 3000

Indications For Use:

The SensiLase™ PAD 3000 provides a noninvasive measurement of Skin Perfusion Pressure (SPP) and Pulse Volume Recording (PVR) waveforms on extremities of patients.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040654